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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/828,558      | 04/21/2004  | Randell L. Mills     | 62248-1             | 5441             |

20736 7590 03/07/2007  
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2000 M STREET NW SUITE 700  
WASHINGTON, DC 20036-3307

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| EXAMINER |
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POWERS, FIONA

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| ART UNIT | PAPER NUMBER |
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1626

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 03/07/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/828,558

Applicant(s)

MILLS ET AL.

Examiner

Fiona T. Powers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-181 is/are pending in the application.
- 4a) Of the above claim(s) 39-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 74,75,78-80,104,128-130,147,153-156,161-164,172 and 181 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**Continuation of Disposition of Claims: Claims rejected are 1-38, 71-73, 76, 77, 81-103, 105-127, 131-146, 148-152, 157-160, 165- 171 and 173-180 .**

Receipt is acknowledged of the preliminary amendment filed November 1, 2004, which has been entered in the file.

Claims 39 to 70 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on December 5, 2006.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
It does not identify the citizenship of each inventor.

The citizenship of inventor Guo-Zhang Wu is not listed.

Claims 128 and 154 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 128 and 154 have not been further treated on the merits.

Claims 24, 30, 35, 36, 72, 73, 76, 77, 79, 80, 94, 104, 121, 127, 129, 130, 147, 153, 155, 156, 161, 163, 172, 175, 177 and 181 are objected to because of the following informalities: claims 24, 30, 35, 73, 76, 77, 79, 80, 94, 104, 121, 127, 129,

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130, 147, 153, 155, 156, 161, 163, 172 and 181 do not end in a period. Claim 30 contains periods within the claim. Only one period at the end should appear. On pages 57, 58 and 60 of claim 36, exclamation points (!) appear within the chemical names. It appears that these "!" should be deleted. On page 58 of claim 36, "platelett" should be -platlet-. In claim 36, on page 52, "whihc" should be -which-. At the end of claim 36, on page 60, "and" should be inserted between "factor" and "tissue". In claim 72, "at least on" should be -at least one-. Claims 175 and 177 are identical. One of these claims should be deleted. Appropriate correction is required.

Claims 20 to 26 and 166 to 181 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 20 to 24 and 166 to 181 are not a further limitation of claim 1 because by performing the steps recited in claim 1, the chemiluminescent moiety A can only be a phthalhydrazide. Claims 25 and 26 are not a further limitation of claim 1 because by performing the steps recited in claim 1, the energy acceptor moiety B can only be a 1,5-diarylpentadiene.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 to 38 and 71 to 73, 76, 77 and 166 to 181 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 to 38, 71, 72 and 166 to 181 are indefinite because by performing the steps recited in claim 1, the chemiluminescent moiety A can only be a phthalhydrazide and the energy acceptor B can only be a 1,5-diarylpentadiene. To overcome this rejection claim 1 should be amended by inserting after "chemiluminescent moiety" -that is a phthalhydrazide- and inserting after "energy acceptor moiety" -that is a 1,5-diarylpentadiene-.

Claim 38 is indefinite because it improperly incorporates by reference essential subject matter.

In claims 73, 76 and 77 the variables  $R^1$ ,  $R^2$ ,  $R^3$  and L are not defined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 to 38, 71, 72, 81 to 103, 105 to 127, 131 to 146, 148 to 152, 157 to 160, 165 to 171 and 173 to 180 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of synthesis of a compound A-B-C wherein A is a chemiluminescent moiety that is a phthalhydrazide, sulfonyloxamide or active oxalate, B is an energy acceptor moiety that is a 1,5-diarylpentadiene and C is Foscarnet, ddc or acycloguanosine, does not reasonably provide enablement for a method of synthesis of a compound A-B-C where A is any chemiluminescent moiety, B is any energy acceptor moiety and C is any biologically active moiety for example, any pharmaceutical or drug. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph are as follows:

1. the nature of the invention,
2. the state of the prior art,

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3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of skill in the art.

See *In re Wands*, 8 USPQ2d 1400.

In the instant case, there is unpredictability in the art and the breadth of the claims encompasses a method of synthesis of a very large group of compounds of the formula A-B-C where A is any chemiluminescent moiety, B is any energy acceptor moiety and C is any biologically active moiety for example, any pharmaceutical or drug. The working examples in the specification are only directed to a method of synthesis of a compound A-B-C wherein A is a chemiluminescent moiety that is a phthalhydrazide, sulfonyloxamide or active oxalate, B is an energy acceptor moiety that is a 1,5-diarylpentadiene and C is Foscarnet, ddc or acycloguanosine. It would require an undue amount of experimentation for one of skill in the art to synthesize the entire scope of compounds encompassed by formula A-B-C as different reactions and reaction conditions would be required.

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Claims 74, 75, 78, 154, 162 and 164 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The references made of record and not relied upon show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Fiona T. Powers*  
Fiona T. Powers  
Primary Examiner  
Art Unit 1626

ftp  
March 2, 2007